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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/142,557 09/11/98 PILARSKI L P-1459(O)

HUGHES ETIGSON
175 COMMERCE VALLEY DRIVE WEST
SUITE 200
THORNHILL ON L3T 7P6
CANADA.

HM22/0913

EXAMINER

FONDA, K

ART UNIT

PAPER NUMBER

1623

14

AIR MAIL

DATE MAILED:

09/13/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/142,557

Applicant(s)

PILARSKI, LINDA MAY

Examiner

Kathleen Kahler Fonda, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 July 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 103, 106-111, 114-126, 130-136, 138, 139, 141, 143 and 144 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 03, 106-111, 114-126, 130-136, 138, 139, 141, 143 and 144 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

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The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of claim 138 as indefinite made in prior Office actions is withdrawn in view of Applicant's amendment.

The rejection of claims 103, 106-111, 114-126, 130-136, 138, 139, 141, 143, and 144 made in prior Office actions under 35 U.S.C. 103(a) HAN et al. (L) in view of FALK et al. (A) is withdrawn. Applicant points out that a library reception stamp for HAN give a date of June 27, 1996. Furthermore, MEDLINE AN 96257839 give a cover date for HAN of July 1996. Thus it appears that HAN is not prior art to the instant claims.

Claims 111, 114, 115, and 136 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

Claim 111 remains indefinite, as set forth in the Office action of 0-30-01 for failing to recite any steps by which the claimed "method for administering" is to be carried out. In skeletal form, the amended claim reads "A method for administering . . . comprising administering" If a

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method for administering is claimed, the body of the claim must do more than simply repeat the preamble in order to be definite.

Although claim 136 as amended no longer lacks antecedent basis, it remains indefinite for one of the reasons stated in the Office actions of 08-09-00 and 01-30-01. Specifically, claim 133, from which claim 136 depends, requires administration of sodium hyaluronate. Thus, recitation of "hyaluronic acid" in place of --hyaluronan--, while curing the antecedent basis problem, still fails to address the indefiniteness which stems from inconsistency between claim 136 and claim 133.

Claims 103, 106-111, 114-126, 130-136, 138, 139, 141, 143, and 144 are again rejected under 35 U.S.C. 103(a), as set forth in the Office actions of 08-09-00 and 01-30-01 as being unpatentable over either HAMANN et al. (K) in view of FALK et al. (A).

Applicant's arguments filed 07-30-01 have been fully considered but they are not persuasive. Applicant argues that HAMANN teaches away from the instant invention because in an assay which, in Applicant's view, would best approximate *in vivo* conditions, HAMANN observed inhibition rather than proliferation at certain concentrations. This argument is not convincing because at best, it indicates that achieving proliferation is

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dosage dependent. Determining a particular appropriate dosage is ordinarily within the level of skill of a person having ordinary skill in the art, and there is no reason to expect that it would not be in this instance. Applicant further argues that neither HAMANN nor FALK teaches release or mobilization of cells. It is not relevant to the inquiry at hand that HAMANN and FALK may not have recognized this particular benefit of administration of hyaluronic acid, because HAMANN suggests and FALK teaches *in vivo* administration. See *Mehl/Biophile Int'l Corp. v. Milgraum*, 52 USPQ2d 1303 (Fed. Cir. 1999).

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Papers relating to this application may be submitted to Technology Center 1600 by facsimile transmission. The number of the fax machine for official papers in Technology Center 1600 is (703) 308-4556. Any document submitted by facsimile transmission will be considered an official communication unless the cover sheet clearly indicates that it is an informal communication.

INTERNET INFORMATION: Secure and confidential access to patent application status information is now available; see <http://www.uspto.gov/ebc/index.html> for more information. Also, <http://www.uspto.gov/web/offices/ac/comp/fin/clonedefault.htm> may be used to pay patent maintenance fees, pay non-filing application fees, and maintain USPTO deposit accounts.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Kathleen Kahler Fonda, at telephone number (703) 308-1620. Examiner Fonda can generally be reached Monday through Thursday from 7:30 a.m. until 12:30 p.m. If the Examiner cannot be reached, questions may be addressed to Supervisory Patent Examiner Gary Geist at (703) 308-1701. Any inquiry of a general nature or relating to the status of this application should be directed to

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the Technology Center 1600 receptionist whose telephone number
is (703) 308-1235.

A handwritten signature in cursive script, reading "Kathleen Kahler Fonda".

Kathleen Kahler Fonda, Ph.D.

Primary Examiner

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